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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/523,857
Filing Date: May 11, 2005
Appellant(s): MANTLE, ROSS E.

/Phil Wiest/
Examiner, Art Unit 3761
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/5/08 appealing from the Office action mailed 1/8/08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4450841	OSTERHOLM	5-1984
3927980	LEONARD	12-1975

6497721	GINSBURG ET AL.	12-2002
5562821	GUITIERREZ-COLLAZO	10-1996
6743218	MAGINOT ET AL.	6-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-9, 11-13, 18, 19, 21-23, 27-30, 32-34, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (US 4,450,841) in view of Leonard (US 3,927,980), and further in view of Ginsburg et al. (US 6,497,721).

3. Osterholm discloses an apparatus for modulating the temperature and pressure within a body cavity by means of recirculating of a biologically compatible liquid, the apparatus comprising a first pump means 18 for infusing liquid at a controlled temperature and flow rate into the cavity, means for monitoring temperature of fluid (14, 40), and means for monitoring pressure of the fluid (18, 38). Osterholm, however, does not disclose that the monitoring means monitor temperature and pressure within the cavity, nor does it teach a second pumping means for withdrawing liquid at a controlled rate from the cavity.

4. Regarding Osterholm's lack of a second pumping means, Leonard discloses an extracorporeal system comprising a first pump 36 capable of infusing a liquid and a second pump 40 capable of withdrawing a liquid at a controlled flow rate (see Figure 1). The use of a plurality of pumps and a liquid storage means allows fluid to be withdrawn from the cavity at a different than it is infused, such that the pressure within the cavity can be controlled. When controlling the pressure within a cavity, is it obvious that pressure changes may be realized by changing the amount of fluid present within the cavity. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the apparatus of Osterholm with the plurality of pumps of Leonard so that the flow rate of fluid into and out of the cavity may be controlled, thereby regulating the pressure within the cavity.

5. Regarding Osterholm's lack of monitors within the cavity, Ginsburg et al. (hereafter "Ginsburg") discloses an apparatus for regional temperature modification wherein cranial pressure and temperature may be monitored and controlled (Column 5,

Lines 58-65, Column 14, Lines 49-59, and Abstract). While Osterholm does disclose the monitoring of temperature and pressure, it is done so within the liquid storage chamber and not within the body. It is obvious that temperature measurements will be more accurate inside the body than in a fluid reservoir. Additionally, taking internal pressure measurements allows the pressure within the cavity to be controlled. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the apparatus of Osterholm with the use of internal pressure and temperature monitoring of Ginsburg in order to more accurately monitor the pressure and temperature inside the cavity, thereby allowing the apparatus to change the flow rate and heat transfer settings accordingly.

6. With respect to Claim 6, Osterholm discloses a liquid storage means (10, 12, 14, 16, and 28) situated between the inflow and outflow catheters. The liquid storage means draws fluid from the outflow catheter, treats the fluid, and pumps the fluid back into the body cavity (see Figure 1).

7. With respect to Claim 7, Osterholm discloses a first catheter (connecting the spinal subarachnoid space 26 and the output collection 28) and a second catheter 30 to withdraw liquid from the cavity to the liquid storage means.

8. With respect to Claims 8 and 9, Osterholm discloses means to oxygenate and adjust the pH of the liquid (Column 14, Line 55 through Column 15, Line 21).

9. With respect to Claim 2, Osterholm in view of Leonard and Ginsburg discloses the apparatus of Claim 1, wherein fluid is circulated out of and back into the body through lumens connected to pumps (see the above rejection). Ginsburg further discloses the use of a dual-lumen catheter comprising an inflow lumen and an outflow lumen to circulate fluid into and out of a body region (see Figure 2). The use of dual-lumen catheters to circulate a liquid or introduce multiple fluids is established in the art because they allow a single incision to be made in the skin, thereby reducing the pain that a patient experiences. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the apparatus of Osterholm in view of Leonard and Ginsburg with Ginsburg's use of a dual lumen catheter because doing so would enable fluid to be circulated in and out of a body while reducing the number of incisions necessary from two to one.

10. With respect to Claims 3-5, Osterholm discloses a further catheter 30 connecting the cavity and the liquid storage means. The further catheter withdraws fluid from a different part of the brain such that treatment may be focused at specific areas of the cavity (Column 13, Lines 4-29). Osterholm, however, does not specifically disclose the use of a pump to withdraw fluid from the cavity through the further catheter. As explained above, Osterholm in view of Leonard and Ginsburg disclose an apparatus for circulating fluids in a body cavity comprising a pump to move fluid through the catheter and pressure and temperature monitoring means that control the pump. This configuration allows fluid to be drawn from the catheter at an optimal rate as determined by the sensors. Therefore, it would have been obvious to one skilled in the art at the

time of invention to combine the further catheter of Osterholm with the catheter pumping and monitoring means of Osterholm in view of Leonard and Ginsburg in order to provide controlled flow from a second position within a body cavity such that treatment may be localized at specific points within the cavity.

11. With respect to Claims 11 and 12, Osterholm in view of Leonard and Ginsburg discloses the device of Claims 1 and 6, and that temperature and pressure sensors may be placed at the tip of a catheter such that they record the temperature and pressure inside a body cavity (see rejection above). The pumps may controlled in order to control the pressure inside the cavity (see Osterholm: Column 14, Lines 28-33). Furthermore, Ginsburg discloses a pump that is responsive to the difference between the temperature in the cavity (reference temperature) and the temperature in the liquid storage means (Column 22, Lines 36-47). Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the device of Osterholm in view of Leonard and Ginsburg with the temperature-based pump control of Ginsburg and the pressure-based pump control of Osterholm because doing so would allow both temperature and pressure to be controlled by altering the flow rate of fluid into and out of the cavity.

12. With respect to Claim 13, Osterholm discloses means 18 responsive to the pressure sensed pressure monitoring means 38. Osterholm, however, does not disclose that said pressure monitoring means are disposed within the cavity. As

explained above, Ginsburg discloses a device wherein temperature and cranial pressure are monitored in order to control the system (Column 14, Lines 49-59). These internal pressure measurements allow the pressure in the system (i.e. speed of the pump) to be controlled such that pressure in the cavity reaches an optimal level. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the apparatus of Osterholm in view of Leonard and Ginsburg with the use of internal pressure and temperature monitoring of Ginsburg in order to more accurately monitor the pressure and temperature inside the cavity, thereby allowing the apparatus to change the flow rate and heat transfer settings accordingly.

13. With respect to Claim 20, Osterholm, Leonard, and Ginsburg disclose the device substantially as claimed (see rejection above), wherein a sensor is placed inside the body in order to monitor temperature. Ginsburg further discloses that the temperature sensor is attached to the tip of the catheter to sense the temperature of fluids in the body (see entire disclosure). Based on the sensed temperature, the system heats or cools the withdrawn fluid to achieve a desired body temperature. The placement of temperature sensors at the distal end of a catheter is well established in the art because it allows the temperature of body fluids at the fluid withdraw point to be easily monitored. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to try modifying the catheter system of Osterholm, Leonard, and Ginsburg with the temperature sensor at the distal tip of the catheter of Ginsburg in order to provide a simple, alternate means for measuring temperature inside the body. Providing the

sensor integrally with the catheter would prevent the need to separately insert a sensor into a body cavity.

14. With respect to Claims 25 and 26, Osterholm, Leonard, and Ginsburg disclose the device substantially as claimed. Leonard further discloses that the device comprises a first recepticle 14 for storing liquid to be introduced into the patient's body, and a second receptacle 12 for collecting liquid removed from the patient's body. The first and second recepticles are coupled by a recirculation line 42. The recirculation line balances the system and protects from over-pressure due to fluid accumulation, therefore ensuring that fluid is able to be constantly infused into the body at the desired rate. For this reason, the use of reservoirs and recirculation lines are extremely common in the art of physiological fluid treatment devices. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Osterholm, Leonard, and Ginsburg with the inlet recepticle, outlet recepticle, and connecting recirculation line of Leonard in order to provide proper fluid and pressure balancing for the system, thereby optimizing the rate of fluid flow to the patient.

15. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm in view of Leonard, and further in view of Ginsburg and Guitierrez-Collazo (US 5,562,821). Osterholm in view of Leonard and Ginsburg disclose the device of Claims 1 and 6 (see rejection above). Osterholm further discloses that the liquid is

sterilized by sterilization unit 32 and harmful chemicals are removed by filter element 12 (see Figure 1) while in the liquid storage means, but does not specifically disclose contaminants are removed by foam fractionation. Guitierrez-Collazo discloses a foam fractionation device that removes contaminents from an aquatic environment by creating a vortex. This method of purification is well established in the art of fluid filtration as a method of removing organic compounds in order to prevent the build-up of bacterial byproducts, which could cause infection (Column 2, Lines 21-30). Therefore, it would have been obvious to one skilled in the art at the time of invention to combine th device of Osterholm in view of Leonard and Ginsburg with the use of a foam fractionator of Guitierrez-Collazo in order to provide an alternate means for removing contaminants from the liquid before returning it to the body.

16. Claims 24, 31, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Osterholm in view of Leonard and Ginsburg, and further in view of Maginot (US 6,743,218). Osterholm, Leonard, and Ginsburg disclose the device substantially as claimed (see rejection above), but do not disclose that the inlet and outlet catheters are arranged as a single dual lumen catheter. Maginot discloses a dual lumen catheter that is used to move fluids in and out of a fluid cavity. The use of dual lumen catheters is extremely common in a wide variety of physiological fluid treatment methods because they allow fluids to be removed from and returned to the body through a single catheter, thereby requiring only a single incision to be made. Therefore, it would have been obvious to one of ordinary skill in the art at the time of

invention to modify the treatment device of Osterholm in view of Leonard and Ginsburg with the dual lumen design of Maginot in order to reduce the number of incisions required, thereby improving patient comfort and reducing the risk of surgical complications.

(10) Response to Argument

1. Regarding the rejection of Claims 1-9 and 11-13 over Osterholm, Leonard, and Ginsburg, appellant argues that "the purpose of Osterholm's stroke treatment apparatus is to provide oxygen and other nutrients to brain tissue, not to modulate the temperature and pressure of the brain" (p. 6). This argument is not persuasive because Osterholm clearly teaches a device that monitors and adjusts temperature and pressure in a patient's brain (see 16, 18, 36, and 38 of Figure 1).

Second, appellant argues that there is no motivation to modify Osterholm with Leonard because Leonard's device supplies blood to arteries and withdraws from veins, which appellant alleges are different cavities. This argument has not been found persuasive because arteries and veins are part of the same circulatory system. When blood is withdrawn from the first pump, the blood pressure in the patient's body will drop unless blood is reinfused through the second pump. Leonard teaches that the use of an inlet pump and an outlet pump allows for improved control over fluid pressure in the fluid line and in the body (Column 1, Lines 55-60 and Column 3, Lines 24-60). Therefore, Leonard generally teaches that the use of two pumps (one inlet, one outlet) to control the flow of fluid through a fluid system allows for improved control over pressure and

flow rate. It is the examiner's position that it would have been obvious to one skilled in the art at the time of invention to combine the apparatus of Osterholm with the plurality of pumps of Leonard so that the flow rate of fluid into and out of the cavity may be controlled, thereby regulating the pressure within the cavity.

Third, appellant argues that there is no motivation to modify Osterholm with Ginsburg because Ginsburg does not monitor the temperature of a cavity to which liquid is infused. This argument has not been found persuasive. Osterhomn teaches a means for monitoring and adjusting pressure and temperature of fluid to be infused into a cavity in a patieny's body. Ginsburg generally teaches the use of body-implanted sensors to monitor temperature and pressure within a cavity (Column 5, Lines 58-65, Column 14, Lines 49-59, and Abstract). Even though the cavity of Ginsburg is a blood vessel, Ginsburg provides motivation to use body-inserted sensors because it allows for precise control of temperature and pressure in a localized area of the body (see Abstract). Therefore, it is the examiner's position that it would have been obvious to one of ordinary skill in the art at the time of invention to modify the apparatus of Osterholm with the use of internal pressure and temperature monitoring of Ginsburg in order to provide alternate means for accurately monitoring the pressure and temperature inside the cavity, thereby allowing the apparatus to change the flow rate and heat transfer settings accordingly.

2. Regarding the rejection of Claims 18, 19, 21-23, 27, and 28 over Osterholm, Leonard, and Ginsburg, appellant argues that the prior art does not teach or suggest (1)

a catheter configured for insertion into the cavity and introduction and removal of liquid from the cavity and (2) one or more sensors positionable in the patient's body so as to sense a condition of liquid in the cavity. This argument has not been found persuasive. Osterholm clearly teaches a catheter (i.e. fluid flow line) that is adapted to introduce and remove fluid from the cavity. Osterholm also teaches sensors that monitor temperature and pressure of the fluid. As discussed above, Ginsburg teaches the use of implanted sensors to monitor and control the temperature and pressure inside a body cavity. Therefore, it is the examiner's position that it would have been obvious to one of ordinary skill in the art at the time of invention to modify the apparatus of Osterholm with the use of internal pressure and temperature monitoring of Ginsburg in order to provide alternate means for accurately monitoring the pressure and temperature inside the cavity, thereby allowing the apparatus to change the flow rate and heat transfer settings accordingly.

3. Regarding the rejection of Claims 28-30 over Osterholm, Leonard, and Ginsburg, appellant argues that that the prior art does not teach or suggest (1) a catheter configured for insertion into the cavity and introduction and removal of liquid from the cavity, (2) one or more sensors positionable in the patient's body so as to sense a condition of liquid in the cavity, and (3) a controlled pumping system operatively coupled to the catheyer to modulate a property of the liquid in response to signals received from the sensors to maintain the biologival parameter of the patient's body within a selected range. These argument has not been found persuasive. Regarding

arguments (1) and (2), see the response to arguments in Section 2 above. Regarding argument (3), Osterholm teaches a controlled pumping system operatively coupled to a variety of sensor means (temperature, pressure, oxygen, chemical) such that the a variety of properties of the liquid are capable of being adjusted to maintain a plurality of desired parameters (see Figure 1). Although Osterholm does not teach an implanted sensor, Ginsburg provides motivation for an implanted sensor, as discussed above.

4. Regarding the rejection of Claims 28-30 over Osterholm, Leonard, and Ginsburg, appellant argues that that the prior art does not teach or suggest (1) a step of monitoring a parameter of liquid within the cavity from a sensor implanted within the patient's body and (2) controlling at least one of temperature, pressure, and flow rate in response to the liquid condition value measured in the monitoring step. This argument has not been found persuasive. Osterholm teaches a method of monitoring pressure, temperature, and flow rate in the fluid line and controlling the temperature, pressure, and flow rate in the fluid line accordingly. As discussed above, Ginsburg provides motivation to provide internal sensors as to more accurately monitor the pressure in the cavity. Therefore, the cited prior art reasonably suggests teh device as claimed.

5. Regarding the rejection of Claim 10 over Osterholm, Leonard, Ginsburg, and Gutierrez, appellant's argument is based on the fact that Gutierrez does not overcome the deficiencies from claim 1. Because the rejection of Claim 1 stands, this argument is rendered moot.

6. Regarding the rejection of Claims 24, 31, 35, and 36 over Osterholm, Leonard, Ginsburg, and Maginot, appellant's argument is based on the fact that Gutierrez does not overcome the deficiencies from claims 18, 28, and 32. Because the rejection of Claims 18, 28, and 32 stands, this argument is rendered moot.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Phil Wiest/

Examiner, Art Unit 3761

Conferees:

/Tatyana Zalukaeva/

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